

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kashmiri et al.

Application No. 09/830,748

Filed: April 30, 2001

For: VARIANTS OF HUMANIZED ANTI-

CARCINOMA MAB CC49

Examiner: Larry Ronald Helms

Date: May 12, 2003

Art Unit: 1642

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to being attached or enclosed herewith are being deposited with the United States Postal Service on May 12, 2003, as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, PO BOX 1450, ALEXANDRIA, VA 22313-1450

Susan Alpert Siegel, Ph.D. Agent for Applicant

TRANSMITTAL LETTER

COMMISSIONER FOR PATENTS PO BOX 1450 ALEXANDRIA, VA 22313-1450

Enclosed for filing in the application referenced above are the following:

☐ Information Disclosure Statement ☐ Form 1449 and references cited thereon (23 references)

The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.

Please return the enclosed postcard to confirm that the items listed above have been received.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

Ву

Susan Alpert Siegel, Ph.D. Registration No. 43,121

One World Trade Center, Suite 1600

121 S.W. Salmon Street Portland, Oregon 97204

Telephone: (503) 226-7391 Facsimile: (503) 228-9446

cc:

Docketing

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

sh re application of: Kashmiri et al.

Application No. 09/830,748

Filed: April 30, 2001

1 4 2003

For: VARIANTS OF HUMANIZED ANTI-

CARCINOMA MAB CC49

Examiner: Larry Ronald Helms

Date: May 12, 2003

Art Unit: 1642

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on May 12, 2003 as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, PO BOX 1450, ALEXANDIA, VA) 22313-1450.

Susan Alpert Siegel, Ph.D. Agent for Applicant

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97(b)(3)

COMMISSIONER FOR PATENTS PO BOX 1450 ALEXANDRIA, VA 22313-1450

Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent. The filing of this Supplemental Information Disclosure Statement should not be construed to be an admission that the information cited in this Statement is, or is considered to be, prior art with respect to the present application.

Applicants filed this Information Disclosure Statement before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this Information Disclosure Statement, please charge any such fees to Deposit Account No. 02-4550. A duplicate copy of this Information Disclosure Statement is enclosed.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By

Susan Alpert Siegel, Ph.D. Registration No. 43,121

One World Trade Center, Suite 1600 121 S.W. Salmon Street Portland, Oregon 97204

Telephone: (503) 226-7391 Facsimile: (503) 228-9446

MAY 1 4 2003

SÛPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

_		
	Attorney Docket Number	4239-61725
	Application Number	09/830,748
	Filing Date	April 30, 2001
	First Named Inventor	Kashmiri
	Art Unit	1642
	Examiner Name	Larry Ronald Helms

U.S. PATENT DOCUMENTS

	5,99	94,511	11/20/00	•
		- ,	11/30/99	Lowman et al.
-	6,05	54,297	4/25/00	Carter et al.
	6,18	30,370	1/30/01	Queen et al.

FOREIGN PATENT DOCUMENTS

Examiner's • Initials*	Cite No. (optional)	Number	Date	Country
		WO 96/13594	5/9/96	
		WO 97/26010	7/24/97	
		WO 99/43816	9/2/99	
Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS		
Hakimi <i>et al.</i> , "Reduced immunogenicity and improved pharmacokine anti-Tac in cynomolgus monkeys," <i>J. Immunol.</i> 147:1352-1359, 1991.			• •	
contributions of indiv 36:1079-1091:1999. Kashmiri <i>et al.</i> , "Dev		R substitutions of a humanized monoclonal antibody (CC49): vidual CDRs to antigen binding and immunogenicity," <i>Mol. Immunol</i> .		
		Kashmiri <i>et al.</i> , "Development of a minimally immunogenic variant of humanized anticarcinoma monoclonal antibody CC49," <i>Crit. Rev. Oncol. Hematol.</i> 38:3-16, 2001.		
	Kashmiri et al., "Generation, characterization, and in vivo studies of humanized anticarcinoma antibody CC49," Hybridoma 14:461-473, 1995. Padlan, "Anatomy of the antibody molecule," Mol. Immunol. 31:169-217, 1994 Reichman et al., "Reshaping human antibodies for therapy," Nature (London) 3 327, 1988.		ion, and in vivo studies of humanized	
			le," Mol. Immunol. 31:169-217, 1994.	
			odies for therapy," Nature (London) 332:323-	

EXAMINER	DATE
SIGNATURE:	CONSIDERED:

^{*} Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

SAS/AC:kam	_		
SAS/AC:kam	05/12/03	4239-61725	187089
	7		

مر المراجع الم
SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT

Attorney Docket Number	4239-61725
Application Number	09/830,748
Filing Date	April 30, 2001
First Named Inventor	Kashmiri
Art Unit	1642
Examiner Name	Larry Ronald Helms

BY APPLICANT	First Named Inventor	Kashmiri	
DI MILIOMY	Art Unit	1642	
	Examiner Name	Larry Ronald Helms	
Saldanha et al., "A single backm	utation in the human kIV frame	work of a previously	
unsuccessfully humanized antibody restores the binding activity and increases the		and increases the	
secretion in cos cells," Mol. Imm			
Schier et al., "Isolation of picom	•	-	
evolution of the complementarity	U U	ter of the antibody	
binding site," J. Mol. Biol. 263:5			
Sha and Xiang, "A heavy-chain		the tumor-associated	
TAG72 antigen," Cancer Biothe			
Sharkey et al., "Evaluation of a complementarity-determining region-grafted (huma			
anti-carcinoembryonic antigen m	onoclonal antibody in preclinic	al and clinical studies,"	
Cancer Res. 55:5935s-5945s.			
	Slavin-Chiorini <i>et al.</i> , "Biological properties of chimeric domain-deleted anticarcino immunoglobulins," <i>Cancer Res.</i> 55(23 Suppl.):5957s-5967s, 1995.		
	· · · · · · · · · · · · · · · · · · ·		
Slavin-Chiorini et al., "A CDR-grafted (humanized) domain-deleted antitur		eted antitumor antibody,"	
	Cancer Biother. Radiopharm. 12:305-316, 1997.		
Tamura et al., "Structural correlates of an anticarcinoma antibody: identificat specificity-determining residues (SDRs) and development of a minimally imr		•	
specificity-determining residues antibody variant by retention of			
Wu et al., "Humanization of a m	Wu et al., "Humanization of a murine monoclonal antibody by simultaneous opti		
of framework and CDR residues," J. Mol. Biol. 294:151-162, 1999.			
	Xiang et al., "Complementarity determining region residues aspartic acid at H55, se		
H95 and tyrosines at H97 and L96 play important roles in the B7		⁷ 2.3 antibody-TAG-72	
	antigen interaction," Protein Eng. 9:539-543, 1996.		
Xiang et al., "Light-chain frames			
plays an important role in influer	icing the TAG72 antigen binding	g," <i>Protein Eng.</i> 12:417-	
421, 1999.			
Xiang et al., "The tyrosine residu	•		
mouse/human chimeric anti-colo		ibutes hydrogen bonding	
to the TAG72 antigen," Cancer I	310ther. 8:253-262, 1993.		

SIGNATURE: CONSIDERED:	EXAMINER SIGNATURE:	DATE CONSIDERED:
------------------------	------------------------	---------------------

^{*} Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.